[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using an Armored Payload and Chimeric Antigen Receptors Targeting GPC3

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Senti Biosciences, Inc. ("Senti") located in South San Francisco, CA**.**

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: David A Lambertson, Ph.D., Senior Technology Transfer Manager at Telephone at (240)-276-5530 or E-mail at david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

The following represents the intellectual property to be licensed under the prospective agreement:

(A) U.S. Provisional Patent Application 61/654,232 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012-0-US-01], PCT Patent Application PCT/US2013/043633 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012-0-PCT-02], Chinese Patent 104520331 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012-0-CN-03], Japanese Patent 6494507 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012-0-JP-04], South Korean Patent Application 10-2014-7037046 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012-0-KR-05], Singapore Patent 11201407972R entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012-0-SG-06], United States Patent 9,409,994 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012-0-US-07], and all continuing U.S. and foreign patents/patent applications for the technology family; and (B) U.S. Provisional Patent Application 62/584,421 entitled “Chimeric Antigen Receptors Targeting Tumor Antigens” [HHS Reference E-016-2018-0-US-01], PCT Patent Application PCT/US2018/059645 entitled “Chimeric Antigen Receptors Targeting Tumor Antigens” [HHS Reference E-016-2018-0-PCT-02], Chinese Patent Application 201880073043.9 entitled “Chimeric Antigen Receptors Targeting Tumor Antigens” [HHS Reference E-016-2018-0-CN-03], European Patent Application 18822526.2 entitled “Chimeric Antigen Receptors Targeting Tumor Antigens” [HHS Reference E-016-2018-0-EP-04],

South Korean Patent Application 10-2020-7014565 entitled “Chimeric Antigen Receptors Targeting Tumor Antigens” [HHS Reference E-016-2018-0-KR-05] and U.S. Patent Application 16/762,459 entitled “Chimeric Antigen Receptors Targeting Tumor Antigens” [HHS Reference E-016-2018-0-US-06], and all continuing U.S. and foreign patents/patent applications for the technology family.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following:

“The development, production and commercialization of a monospecific chimeric antigen receptor (CAR)-based immunotherapy for the prophylaxis and treatment of GPC3-expressing human cancers using unmodified, allogeneic NK cells transduced with a viral vector that expresses a CAR and a gene circuit regulating the expression of one or more armoring payloads, wherein:

1) the CAR includes:
    a. a single antigen specificity comprising at least the complementary determining region (CDR) sequences of the anti-GPC3 antibody known as YP7, and
    b. an intracellular signaling domain;
2) the gene circuit includes either a) a synthetic transcription factor that is stabilized or activated by a small molecule drug or environmental signal, or b) a synthetic promoter element that is responsive to a small molecule drug or environmental signal; and

3) the armored payload is selected from:

a. an immune-stimulating cytokine,

b. a chemokine,

c. a growth factor,

d. a co-activation molecule, and

e. a tumor microenvironment modulator.

The Licensed Field of Use specifically excludes the use of autologous T cells or T cells that have been genetically modified to become allogeneic. For clarity "allogeneic" means the cells are from a donor that is not the recipient and the term "unmodified" means that no genetic engineering with genome editing tools is performed."

This technology discloses the development of chimeric antigen receptors that recognize the glypican3 (GPC3) cell surface protein. GPC3 is expressed on the cell surface of several solid tumors, including liver cancers (such as hepatocellular cancer (HCC)), certain ovarian cancers, and neuroblastomas. Although the FDA has approved certain therapies for the treatment of liver cancer, those therapies only provide a minimal increase in the life expectancy of patients. The development of a new therapeutic targeting GPC3 will benefit public health by providing an improved and more effective treatment for patients.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published

notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated September 23, 2020.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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